

Remarks:

Claims 1, 11, 12, 20, 23-37, 39-64 and 71-78 are pending. Claims 13-19, 21, 23, 65 and 70 have been cancelled. A non-final Office Action of September 12, 2007 ("the Office Action") rejected all claims.

The Office Action objected to claims 66, 71-72, 75 and 77 for containing improper periods.

Claims 23-25, 49-64, 66-68, and 72 and 78 were rejected under 35 U.S.C. § 112, paragraph 2 for indefiniteness for using the term "about" in combination with such terms as "less than," "between," and "from." Claims 1-2, 11-12, 20, 23-37, 39-48 and 62-64 were rejected under 35 U.S.C. § 112, paragraph 2 for indefiniteness for using the term "namely poloxamer 188."

Claims 1, 11-12, 20, 23-37, 39-64 and 71-74 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,452,817 to Glen et al. ("Glen") in view of PCT Publication No. WO 03/017977 to Meadow et al. ("Meadow") further in view of U.S. Patent No. 6,140,374 to May et al. ("May") further in view of U.S. No. 6,743,436 to Lee et al. ("Lee"). Claims 75-78 were also rejected under 35 U.S.C. § 103(a) as unpatentable over Glen in view of Meadow further in view of May further in view of Lee.

Claim Objection: use of periods

Applicants have amended claims 66, 71, 72, 75, and 77 to eliminate the objected to periods. Withdrawal of the objection is respectfully requested.

Rejection under 35 U.S.C. § 112 ¶2: "about"

Applicants have amended claims 23-26, 49, 50, 59, 63, 64, 66, 72, and 78 to delete the term "about" when used in combination with "less than," "between," and "from." Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 112 ¶2: "a block copolymer, namely poloxamer 188"

Applicants have amended pending claims 1, 11, 12, 71, and 72 to change the phrase "a block copolymer, namely poloxamer 188" to "poloxamer 188." Withdrawal of this rejection is respectfully requested.

Prior art rejections under 35 U.S.C. § 103(a) relying on Glen

All independent claims of the pending application are limited to an aqueous propofol formulation with up to 15% excipients which is clear to the naked eye. The Office Action cited to col. 6, lines 6-8 of Glen as a basis for teaching a preparation of a clear solution. The sentence Applicants believe the Office Action refers to is underlined in the quoted passage from Glen below. The Office Action fails to recognize, however, that the sentence prior to the Glen's description of a "resulting clear solution" states that the composition described includes Cremophor:

EXAMPLE 9

A stirred mixture of 2,6-diisopropylphenol (2g.), polyethylene glycol 200 (10g.) and 'Cremophor' RH40 (10g.) is gently heated until a homogenous mixture is obtained. Water for injection (78 g.) is added portionwise, and the resulting clear solution is sterilized by passage through a bacterial filter (cellulose ester membrane, pore size 0.22μ.). There is thus obtained a sterile composition suitable for parenteral administration to a warm-blooded animal.

Glen, col. 6, lines 6-8. Glen itself describes both Cremophor EL and Cremophor RH40 as a "polyoxyethylene castor oil derivative." Glen, col. 3, lines 26-28. A formulation using Cremophor RH40 as a solvent, therefore, falls outside Applicants' claim limitations in each of its independent claims: "an aqueous formulation" (claims 1,49,66, 72, and 77); "lipid-free" (claim 71); and "aqueous composition" (claim 75).

Moreover, the cited Glen example discloses a composition whose excipient concentration totals 20% which substantially exceeds Applicants' claim limitation of up to 15% excipients.

All of the Office Action's prior art rejections therefore improperly rely upon Glen for a teaching of preparing an aqueous clear solution. The Meadow, May and Lee references, taken singly or in combination, fail to provide any information, which in combination with Glen, would inform one of ordinary skill in the art how to make a clear aqueous propofol composition with less than 15% excipients, and which is free of the problems associated with the use of lipid/oil emulsions, as discussed in detail in the Background of the Invention at pages 1-3 of Applicants' specification as filed. Applicants respectfully submit that on these grounds alone, all of the prior art rejections are improper and should be withdrawn.

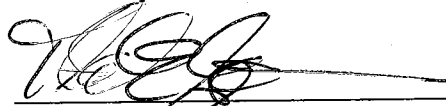
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Conclusion

For the foregoing reasons, Applicants believe their claims as amended are in condition for allowance. Early and favorable notification to this effect is respectfully requested.

Respectfully submitted,



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The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

I hereby certify that this correspondence is being electronically transmitted to: Commissioner for Patents on:

November 26, 2007



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